IN THE

Supreme Court of the United States

October Term, 1979
No. 79-136

SIDNEY A. DIAMOND, Commissioner of Patents and Trademarks,

Petitioner,

vs.

ANANDA M. CHAKRABARTY.

BRIEF ON BEHALF OF GENENTECH, INC., AMICUS CURIAE.

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> *"'Is it conceivalbe' I asked, 'that one day we shall create, in effect, biological machines—systems that can be used for productive purposes and will be composed not of plastic or metal parts, but of living organisms?' His answer was . . . unequivocal: 'We are already there. The great future of industry will come from biology.'"*[1]

Interest of Amicus Curiae.

Genentech is a small venture capital corporation founded in California in 1976 to convert the promise of recombinant DNA technology into received benefits in areas as diverse as medicine, agriculture and energy. Research funded by Genentech at the City of Hope

[1]Toffler, *Future Shock*, 195 (Bantam ed., N.Y. 1970), reporting a conversation with Arne Tiselius, president of the Nobel Foundation.

National Medical Center in Duarte, California and elsewhere resulted in the creation, for the first time anywhere, of a bacterial organism capable of producing a human hormone. In subsequent testimony before Congress that achievement was hailed as a "scientific triumph of the first order" by Phillip Handler, president of the National Academy of Sciences, and as "astonishing" by Paul Berg, himself a pioneer in the field.[2]

More recently, Genentech and its City of Hope collaborators succeeded, with other genetically altered bacteria, in producing no less than human insulin itself. Press reaction included this, from the September 8, 1978 editorial pages of the *Los Angeles Times*:

> "The important and laudable achievement in insulin copying supports the positive expectations of scientists to the potential benefit of millions of persons now living and yet to be born."

And in July of 1979, in what *The Economist* hailed as a "remarkable feat"[3], Genentech married natural and synthetic DNA to create a microorganism capable of producing human growth hormone. The result will be unlimited availability of a substance heretofore in critical short supply for the treatment of dwarfism and, possibly, one useful for bone fracture and burn therapy as well.

Variously in collaboration with other private parties, educational institutions and, for that matter, agencies of the United States Government, Genentech is continuing research aimed at the beneficial application

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[2]*Hearings on Regulation of Recombinant DNA Research before the House Subcommittee on Science, Technology and Space,* 95th Congress 1st Sess. 27, 55 (1977).

[3]Issue of July 14, 1979 at 88.

of recombinant DNA technology in cancer treatment, in the creation of vaccines against a wide variety of viral diseases, and in other fields.

It should be clear that the issue before this Court transcends the narrow interests of the parties and that the Court's decision will have a profound impact on, for example, the question whether investments in research expenditures and recombinant DNA technology should be made in view of the character of patent protection available. In Genentech's case the patent incentive did, and doubtless elsewhere it will, prove to be an important if not indispensable factor in attracting private support for life-giving research. And where the Patent System facilitates the interposition of small but fruitful companies like Genentech in pharmaceutical and other industries traditionally dominated by major concerns, it operates to best purpose, as an essentially pro-competitive mechanism.

Having delivered very substantial benefits to the public in reliance on the patent incentive, Genentech is vitally interested in continued operation of the quid pro quo principle upon which the Patent System is based.

All parties have consented to the filing of this brief Amicus by letter, the originals of which are being filed concurrently with the clerk.

The Issues Presented.

The issues addressed by this amicus are:

Whether it is in the public interest to afford patents on newly manufactured microorganisms;

Whether, in the alternative, any public interest could be served by denying them; and

Whether it is appropriate for this Court, before Congress has acted, to essay the task of subtracting any particular technology from the compass of a patent statute plainly written to embrace technologies unknown to Congress at the time of passage.

In the view of this amicus, and particularly following the dismissal of *Diamond v. Bergy*, No. 79-136 as moot, the issue before the Court is decidedly not one of patenting either principles of nature or anything akin to them. Compare *Parker v. Flook*, 437 U.S. 584 (1978). The Chakrabarty microorganism, like those created by Genentech, is remarkable precisely because it is found nowhere in nature. Instead, at least in respect to what makes it useful, it was called into being solely by the hands of man.

Summary of Argument.

American experience has shown that the Patent System of the United States is one of the most ingenious engines for the inspiration of new technology ever conceived. In large part, the ingenuity of the system is attributable to two of its special characteristics.

First, the system seeks not to catalogue the past, but rather to compass the future. It perceives that the permissible subjects of patents are as broad as man's technological grasp, and so is written out in broad and forward-looking terms with the aim of extending our reach in every useful direction. Its purpose is not extended, but rather fulfilled, when a new-born technology comes within its purview.

Secondly, the Patent System is, out of necessity, neutral. It cannot be too finely tuned to the kind

(as distinguished from quality) of creation involved, if it is to achieve its task of encouraging the dissemination of what is new and imaginative and useful, so it can be finally judged in the marketplace of ideas and things. Most particularly must it abjure prior restraints, because they chill expression in literature and science alike. The neutrality of the Patent and Trademark Office requires that it leave to other agencies the regulation of technology, after the fact of its creation. Its different job is to inspire creations of every kind, and then before the fact of their creation.

Petitioner's argument from the controversiality of recombinant DNA technology is both misleading and irrelevant. It is misleading because the controversy has largely dissipated. It is irrelevant because controversiality cannot be made the judge of patentability, else the most revolutionary inventions would go unrewarded and the domain of patent law would be relegated to that of gadgeteers alone.

It is Petitioner, not Respondent, that would cast this Court in a legislative role. This Court is ill-equipped to determine when and then to what extent the needs of society require that any given technology be deleted from the broad compass of the patent laws. Congress, on the other hand, has that capability and has exercised it in the past, both prospectively and, as to already issued patents, retrospectively. See 42 U.S.C. 2181(a).

The new biology holds enormous promise in application for the public good. Much tangible benefit is already in hand. Despite the contrary view of Amicus The Peoples Business Commission, it *is* the job of the Patent System to generate greater momentum in such research and in all research that promises advan-

tage. Regulating the product of research must fall to agencies other than the Patent and Trademark Office, which is itself inept as a regulatory tool. In any event, no regulatory purpose would be served by denying patents on microorganisms while continuing to grant them on processes of creating and using such organisms; while permitting academic research to go forward indifferent to either profit or patents; and while permitting even industrial practitioners to seek trade secret alternatives, so defeating the role of the Patent System as an information clearinghouse.

On the other hand, grant of microorganism patent protection is required to avoid opportunities for cynical evasion of patent laws as they attach to processes alone. Nothing in the legislative history prohibits such patents. Instead, the logic and greater purpose of the Patent System compels them.

Petitioner Is Seeking Judicial Legislation in Policy Areas Unsuited to Judicial Consideration, Proceeding From a Premise Wholly at Odds With the Logic of a Patent System.

No one will dispute the notion that patent laws are written to incent the creation of things outside the contemplation of those who enact such laws. Perforce, patent laws are written in large and prospective terms, so as to include "anything under the sun that is made by man".[4] The genius of the patent system is that it extends and enlarges useful technology. Having been designed to inspire new technology, the system is not itself "extended", but rather fulfilled, when the

[4]*In re Chakrabarty*, 596 F.2d 952, 987 (1979), quoting both House and Senate reports accompanying the 1952 enactment of Title 35, U.S.C.

desired results are attained and new science comes under its protection.

The best science and the best of invention is that properly described as "revolutionary", a term that bespeaks profound and often sudden change in the way men live their lives. A common consequence of revolutionary invention is widespread impact at every level of society. Undue caution in admitting inventions of that character to the protection of patent would, in the end, fashion a result antithetical to that envisioned by Congress. Only the most mundane innovation would be rewarded, and the grant of patents confined to the very "gadgets" reviled by Justice Douglas, concurring in *Great A. & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 156 (1950).

Revolutions in science generate "empirical data" of the sort referred to by Justice Stevens, writing for the Court in *Parker v. Flook*, 437 U.S. 585, 595 (1978), in direct proportion to their impact on society. We agree that such data is grist for the Congressional mill, and ill-suited to assessment by the Supreme Court. For precisely that reason, we submit that if newly created technologies of wide-ranging impact are to be subtracted from the broad compass of patentability, it is Congress that in the first instance should essay that task. To paraphrase the brief of Petitioner.[5]

> "Congress, rather than the judiciary, is empowered and is best able to resolve the complex social, economic, and scientific questions frequently involved in such decisions, and, if [a deletion] is to be made, to tailor the statute to achieve precisely the desired ends."

[5]Brief for the Petitioner at 9-10.

Congress has proven its ability to tailor the patent statute in exactly that fashion, as witness 42 U.S.C. 2181(a):

> "No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor."

When that section was enacted atomic research was controversial in all its parts, and it remains so even to the present day. Yet Congress had the facility, as this Court does not, to limit its "tailoring" of the Patent System by the dictates of policy in a complex field, and it exercised it so as to proscribe only certain patents, while permitting such others as those later issued to Glenn Seaborg[6] for the creation of the isotopes that are Elements 95 and 96 of the Periodic Table.[7] The surgical precision of Congress' action in this regard stands in sharp contrast to the meat-ax approach Petitioner now urges. Thus, Petitioner would have the Court proscribe the grant of patents across the full length and breadth of a "vast"[8] field, one whose span includes everything from beer-making to gene-splicing, and then to do so because a *part* of that field is "controversial".

Endless mischief would result from adoption of Petitioner's approach to resolving "patent-ability" questions by reference to policies outside those embodied in

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[6]U.S. patents 3,156,523 and 3,161,462.

[7]Indeed, it was the Government itself which applied for and obtained those patents, Seaborg being its employee.

[8]Brief of the Petitioner at 20.

the Patent Act itself. Each time there arose a pioneer technology of societal consequence, courts would be asked to constrict the patent laws until Congress could adjust the competing policy considerations involved. The job of Congress would reduce to more or less piecemeal restoration of the Patent System, technology by technology. When each technology was restored by Congress to its rightful place within the broad and forward-looking language of 35 U.S.C. 101, only the efforts of those who created the technology would go unrewarded, for their patents would have in the meantime been denied. Petitioner's argument from caution in "extending" the patent incentive leads ineluctably to this absurd conclusion.

It is one thing to decry interstitial additions by the judiciary to the patent laws, as does the dissent below.[9] It is quite another to urge, as does Petitioner, interstitial deletion of whole technologies from the operation of those laws. The latter asks the Court to legislate in the stead of Congress, and then in areas peculiarly unsuited for judicial treatment. Most particularly should the Court eschew such action when Congress has demonstrated, as it did in enacting 42 U.S.C. 2181(a), its refined ability to both adjust the scope of the patent laws and to revoke patents whose interim grant appears to it, in retrospect, to have been improvident from the standpoint of policy.

The Argument From Controversiality Is Misleading.

Both Petitioner and Amicus, the Peoples Business Commission (PBC), refer repeatedly to the "controversial" aspects of genetic engineering, as if controversy

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[9]*In re Chakrabarty*, 596 F.2d 952, 1002 (Miller, J., dissenting).

were to be made the judge of patentability. The argument from controversy, we suggest, is both misleading and irrelevant. To begin with, animal cloning, test tube insemination and other extravagances have nothing to do with the minute concerns of Chakrabarty, and those in turn have nothing to do with gene-splicing, which alone has generated all the controversy. Even the concern over recombinant DNA technology has, we think, been greatly overblown in the briefs favoring reversal. Though hotly debated just a few years ago, DNA technology "is now in wide use" and, according to Dr. Walter Gilbert of Harvard University, "worries about the dangers of genetic engineering have all but disappeared".[10] In fact, the Director of the National Institutes of Health has approved the large-scale production of insulin by recombinant DNA organisms.[11] In fact, at last count the same Government agency was itself funding fully 717 research projects in the field, to the tune of some 91.5 millions; preliminary studies conducted by the Government have reportedly failed to demonstrate any significant danger associated with recombinant DNA research.[12] Against a backdrop of active promotion of such research by European governments and concern over possible loss of this country's technological lead in the area, a spokesman for Congress' Office of Technology Assessment has suggested

[10]As quoted in " 'Glamour Stock' Could Help Cancer Patients", *Los Angeles Times*, issue of January 21, 1980, Part I, pp. 3, 16.

[11]Letter dated December 13, 1979, Elizabeth Milewski, Scientist Administrator, Office of Recombinant DNA Activities to Dennis Kleid, Chairman, Biosafety Committee, Genentech, Inc.

[12]"Where Genetic Engineering Will Change Industry", *Business Week*, October 22, 1979, 160, 164.

that "government's stance may change from regulation to promotion" of the science.[13] And while Petitioner suggests[14] that it was "continuing controversy" that led the National Institutes of Health to revise its guidelines for research in the area, it was actually the *diminution* of that controversy which led the agency to significantly *relax* those very guidelines.[15]

The Argument From Antagonism to Science.

The attempt to cast this Court in a legislative role is nowhere more evident than in the brief amicus of the Peoples Business Commission (PBC), whose essentially Luddite philosophy[16] would have the Court stand the Patent System on its head, denying patents so as to avoid

> ". . . generating a greater momentum in research and development of genetic engineering technologies . . . [which] . . . in turn, will lead to the rapid proliferation of genetic techniques in the areas of energy, agriculture, medicine, industrial processes and many other aspects of the nation's economic life."[17]

But the question before the Court is neither one of ethics, nor philosophy, nor politics. It is one of statutory interpretation, of grammar leavened with reason. Despite the invitation of PBC, it is not for this Court

[13]*Id.*, quoting Zsolt Harsanyi.

[14]Brief for the Petitioner at 19.

[15]Op. cit. supra, n.12.

[16]The Luddites of early nineteenth century England sought to prevent the spread of labor-saving machinery by the simple expedient of destroying it. For industrial purposes, bacteria that produce human insulin can be regarded as life-saving machinery.

[17]Brief Amicus Curiae of Peoples Business Commission at 3.

to question Congress' wisdom in enacting either the Plant Patent Act[18] or the broader provisions of 35 U.S.C. 101, nor to attempt, like King Canute, to command the tide of technological development.

It is true that genetic engineering is pregnant with potential for altering the human condition. As advances in electronics and plastics led to the implantation of pacemakers and artificial heart valves, so advances in genetics could one day lead, by gene transplants, to the elimination of sickle cell anemia, Tay-Sachs and other genetic diseases. But to suggest, as PBC does, that affirmance of the decision below would bind the Court to construe the Act as permitting patents on all forms of life, even "a human being manufactured to desired specifications"[19] extends literalism beyond reason. One might as well argue that the definition of "meat food products" in 7 U.S.C. 182(3) extends to anthropophagy because it can be literally construed as inclusive of human parts, or that because humans are members of the kingdom Animalia, the Secretary of Agriculture is empowered under the Animal Welfare Act of 1970 "to protect the owners of [humans], from the theft of their [humans],"[20] so resurrecting the fugitive slave laws. The patentability of homunculi[21] is not the issue before the Court, and altruism is misplaced if, on behalf of invisible bacteria that can be freeze-dried to a powder having no semblance of livingness, it argues for the dissuasion of life-giving research.

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[18]Plant Patent Act of 1930, 35 U.S.C. 161 et seq.

[19]Op. cit. supra, n.17, at 25.

[20]See 7 U.S.C. 2131, 2132(g).

[21]Manikins made in flasks by alchemists.

PBC asserts "the public's right to a diversified gene pool composed of naturally occurring life forms"[22]. It wants noting that the naturally occurring life forms most likely to be impacted by the flowering of recombinant DNA technology are those no one will miss at all, deadly vectors associated with such horrific diseases as Lassa Fever, the scourge of Southern Africa; Influenza, which in 1918 slew more than died in the Great War; Epstein-Barr virus, which potentiates one form of cancer in blacks, another in Orientals, and causes mononucleosis in Caucasians; rabies; shingles; foot and mouth disease; and endless others. Even cancers could fall across a broad front, if the promise of interferon produced by recombinant microorganisms holds true.[23]

At bottom, it is clearly in the public's interest to retain patent incentives for inventions in the life sciences in general, and in recombinant DNA technology in particular. If controls are to be imposed on research in those areas, judicial abandonment of the patent reward is not the way to do it. Congress has proven,

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[22]Brief Amicus Curiae of Peoples Business Commission at 13. The accompanying argument that patenting microorganisms could diminish the 'diversity of the gene pool' on planet earth can scarcely be credited, when any shovel-full of backyard sod can yield micro-organic life in endless variety, and when genetic engineering itself permits the creation of new varieties, so tending toward greater and more useful diversity.

[23]Interferon is produced in the body to stimulate defense mechanisms against cancers and viruses. Small amounts have been conventionally produced in the laboratory at enormous expense, but recombinant DNA technology may yield a cheap and plentiful source of the material. Just weeks after the filing of Petitioner's brief, a precursor form of interferon was reportedly made in that way by altered bacteria. "Scientists Produce Protein in Laboratory," *The Los Angeles Times*, edition of January 17, 1980, Part I, p.28. The achievement was reported by Biogen, S.A. which, like Amicus, is a small venture capital company.

time and again, its ability to devise more suitable means of control, as witness a host of regulatory agencies. The more so should such questions be left to future Congresses where the record so far in hand is overflowing with evidence of the beneficial practice of recombinant DNA technology, yet contains not a single instance of any associated harm.

The Denial of Patents on Microorganisms Would Accomplish No Regulatory Purpose.

It can readily be demonstrated that the denial of patents on microorganisms would serve no public interest at all, let alone those for which Petitioner and PBC contend in particular.

To begin with, denial would not diminish the administrative burden of patent examination one iota. Whether the patent claim is directed to an oil-degrading microorganism itself or, say, to a method of combating oil spills that involves deploying a mixture of organism and straw on a spill, the same issues of novelty, utility and unobviousness must be resolved, and in either case the organism must be described and distinguished from the things that have gone before.

Again, it is idle to speculate that denial of patents on microorganisms would be an effective means of curbing their construction, when everyone agrees that patents can continue to issue on methods of constructing them or, more commonly, methods of using them in industry.

Where the limitations of process patents did discourage patent filings, work at an industrial level would, perchance, go forward anyway. As one commercial practitioner has suggested, "you keep your proprietary

strains under lock and key"[24]; that is, forever a trade secret. Were this to happen, the only result would be defeat of one principal purpose of the Patent System —to enhance learning through encouraging disclosure of useful information.

And if the diminution of meaningful patent protection did act as a disincentive to industrial exploitation, no corresponding diminution in biohazard, if indeed any exists, would result. That is so because the controversy over hazard has nothing to do with patents. A biohazardous experiment involving bacteria would be as dangerous if practiced at a laboratory bench in academe as when done at large in industry—perhaps more so, through inattention to the economic consequences of carelessness. Academic and industrial hazard in this area, if it exists at all, is at least in parity. A single virulent organism escaping a University laboratory could rival, virtually overnight, a million-fold escape from a factory. The point is that the denial of patents could inhibit only industrial application of the new science, perhaps the most useful kind. Academicians could continue equally "hazardous" experimentation, indifferent to either profit or patents.

Finally, there is the alternative of patents on plasmids themselves. Plasmids in recombinant bacteria are like carburetors in engines. Properly installed, they permit the bacterial engine to cough into useful life, producing the precious substances whose genetic information they encode. But plasmids are absolutely inanimate. Each building block of the plasmid (and plasmids can be built) is an absolutely dead bench chemical. All of

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[24]"Where Genetic Engineering Will Change Industry", *Business Week*, October 22, 1979, 160, 172 (quoting Leslie Glick, of Genex).

the building blocks in the aggregate are little else. The chemical composition of the plasmid they form is absolutely definable. By every imaginable test, the new plasmids that confer near-miraculous properties on everyday organisms ought to be patentable, just like any other man-made chemical of value. And just as someone who makes, uses or sells an automobile containing a patented carburetor can be sued, so too one who makes, uses or sells a bacterium containing a patented plasmid should be be subject to suit for infringement.

Two things remain to be said about plasmids.

First, pending the resolution of the *Chakrabarty* matter, the Patent and Trademark Office has suspended the examination of patent applications that claim plasmids[25], despite the universal practice in this country of granting patents on inanimate chemical substances and despite the fact that no claim to a plasmid is before this Court. Even an adverse opinion of the Court with regard to the patentability of living things, then, should be careful to preserve the patentability of new but dead chemicals, like plasmids, that meet all the normal criteria of patentability. It is interesting to observe that in the Chakrabarty application the Patent and Trademark Office proved quite willing to grant claims directed to the combination of living organisms and straw, presumably for use in combating oil spills. Can it be said that Congress intended patents on living organisms inside inanimate bits of straw but prohibited them in the case of inanimate bits of chemical inside microorganisms, or are we beginning to draw distinctions that border on the silly?

[25]Private Communication, Examiner A. E. Tannenholtz to the Author, November 13, 1978.

Secondly, the continuing availability of patents on plasmids undercuts the proposal by PBC that this Court's decision be aimed at disincenting the practice of genetic engineering. If plasmids are patentable *in se*, and the Patent and Trademark Office has failed to articulate any reason why they are not, then the practitioners of recombinant DNA technology will be largely unaffected by a ban of patents on microorganisms.[26] Ironically, only those in more conventional fermentation industries will suffer because in those, new microorganisms are gotten in other ways, without the creation of new and independently patentable plasmids.

At bottom, the Patent System is an ingenious vehicle for the inspiration of new technologies. It is an inept tool for their regulation and the attempt to surround it with a regulatory aura, because illogical, is deserving of rejection.

Microorganism Protection Is Required if Cynical Evasion of the Patent Laws Is to Be Avoided.

The fear has been widely expressed that the United States increasingly is losing its technological lead, and that the loss of that lead can be expected to severely

[26]The plasmid question, we add, offers the Court an interesting opportunity to accommodate the interests of both parties in the present matter. *Nothing* in the legislative history of the Patent Act could be construed as proscribing patents on dead chemicals like plasmids. The grant of patents on plasmids could satisfy the needs of a burgeoning and bountiful industry, without reaching the issue of patents on life forms of any kind, let alone higher forms. And although no "plasmid" question is before the Court, the predisposition of the Patent and Trademark Office referred to in the text (which is tied by it directly to the outcome of the present matter) should command both the attention of this Court and care in phrasing its opinion.

impact America's balance of payments and other indicia of economic health. And yet, increasingly, that picture is brightening. According to one commentator:

> "[I]n newer industries the level of research is high and American innovation is the envy of the world."[27]

And, of course, one of the new industries to which the author points is genetic engineering itself. In another article,[28] encouragingly entitled "U.S. Innovation: It's Better Than You Think," the authors find increasing evidence that new enterprises, most particularly in "the exciting science of genetic engineering", are behind a resurgence of domestic innovation. The encouragement of domestic innovation is important, and that can best be done by a strengthened patent system, as both Congress and the President have agreed.[29] In the important field of genetic engineering, that system would be best strengthened or, for that matter, restored by the grant of patents on microorganisms.

Virtually every one of the most remarkable feats of recombinant DNA technology has involved the creation of a new microorganism. But once a single microorganism has been created, in the culmination of what may have been years of work, the process of creation may need never be repeated because, once made,

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[27]"Innovation—Has America Lost Its Edge", *Newsweek*, June 4, 1979, 58, 59.

[28]*Dun's Review*, March, 1979, at 55.

[29]125 Cong. Rec. H22, 912 (daily ed. Feb. 27, 1979); 430 BNA Patent, Trademark & Copyright Journal (BNA); 125 Cong. Rec. 567, 6715 (daily ed. May 24, 1979); Industrial Innovation Coordinating Committee Subcommittee on Patent and Information Policy, Draft Report on Patent Policy §2 (III) (1978); 430 Patent, Trademark & Copyright Journal (BNA) A-2.

the microbe does all the work. It reproduces itself and its new capabilities, time and again. The process can go on indefinitely, certainly throughout the seventeen year term of a patent that may in the meantime have issued.

Absent patent protection on the microorganism itself or, at the least, on its key components,[30] numerous opportunities will arise under which others:

> ". . . would then be allowed to reap the fruits of the American economy—technology, labor, materials, etc.—but would not be subject to the responsibilities of the American patent laws."[31]

After disclosure of the invention whose practice creates the organism, but before actual grant of the patent, others could practice the invention *once*, making an organism that would thereafter perpetuate itself without infringing the later-issued patent. Again, even after the process patent had issued, another could repeat the process outside our borders and beyond the reach of the patent. The resulting organism and its progeny could then be freely introduced to the United States, leaving the process patent holder to his remedy, uncertain at best, in proceedings before the International Trade Commission.[32] Indeed, in the special circumstances of microbiological patenting, it could become possible for the cynical "infringer" to make no organism at all, but rather to obtain and use the inventor's own microorganism from a culture collection in which it has been deposited to satisfy the disclosure require-

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[30]See text accompanying note 26, supra.

[31]*Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 534 (Blackmun, J., in dissent, quoting the opinion of the Fifth Circuit in the same matter, 443 F.2d 936, 939).

[32]See 19 U.S.C. 1337, 1337a.

ments of the Patent Act.[33] Here the holder of a patent confined only to the process by which his micro-organism was created must, absent affirmance of the decision below, sit idly by while another uses that very organism to compete with him in producing an end-product that is itself unpatentable because earlier available from other sources. That is so because the law at present prohibits any restriction on third-party use of deposited organisms, once the patent has issued, and instead then leaves the creator of the organism to his infringement remedy.[34] Absent claims on the organism itself and in the circumstances described, that remedy may be nonexistent.

The iniquitous evasion of the patent laws that could result can be avoided by confirming in inventors their right to effective patent protection on the products of their often-stupendous labors, even when those products are "alive". And to do so requires no extra-territorial extension of the patent laws, as was sought in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), but rather only that their purposes be effectively implemented *within* our borders.

The Argument From Legislative History.

It should come as no surprise to Petitioner that the decision below is the first holding of its kind in almost 190 years of American patent jurisprudence.[35] The question has simply never before come before any court, and under Article III of the Constitution the courts are bound, case-by-case, to resolve only

[33]*In re Argoudelis*, 434 F.2d 1390 (CCPA 1970).

[34]*Feldman v. Aunstrup*, 517 F.2d 1351 (CCPA 1975).

[35]But see Brief for the Petitioner at 13.

the controversies that parties put before them. Petitioner has accordingly been obliged to mine not any body of judicial precedent, but rather a narrow and, in the view of this Amicus, vanishing vein of legislative history.

We believe that the pertinent legislative history (or, in the present case, essential non-history) of the Patent Act reduces to a small number of common-sense propositions apparent from the brief of Respondent and those of other amici:

First, there is no meaningful evidence suggesting that in enacting 35 U.S.C. 101 and its predecessors Congress thought anything about the patentability of microorganisms, either yea or nay. Instead, it clearly sought by broad language to encompass every *new* and useful process and tangible thing that could meet the criteria, including description criteria, of the general patent laws.

Secondly, Congress enacted the Plant Patent Act[36] to broaden the availability of patents, so as to satisfy plant developers otherwise unable to protect their creations because of product of nature and descriptional difficulties arising under the general patent laws.

Thirdly, the exclusion of bacteria from the Plant Variety Protection Act[37] was, pretty clearly, no more than Congressional codification of the decision in *In re Arzberger*, 112 F.2d 834 (CCPA 1940), holding that bacteria were not "plants". That exclusion says nothing contrary to patentability of microorganisms under the general patent laws, in the event they could

[36]Plant Patent Act of 1930, 35 U.S.C. 161 et seq.

[37]Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542, 7 U.S.C. 2321 *et seq.*

conform to utility, novelty, non-obviousness and the more rigid description requirements of those laws.

Suppose that when some Congress had before it the job of enacting or amending the patent laws this testimony had come before it:

> "There exists, out in the future, a new science whose application could result in giant strides toward the elimination of disease, and of hunger, and the creation of whole new energy sources. It can be discovered and applied to those ends if the patent laws you enact are broadly drawn so as to encompass, and to incent, acts of invention that will bring the new science into view."

Would there later be any doubt that by the broad language Congress *did* use in 35 U.S.C. 101 it intended to incent the attainment of those very goals? Would there be any doubt that it intended to encompass the new science, even though its workings remained unknown when the law was drawn? And is there any doubt but that Congresses of the past *did* have salutary goals like those in mind every time the patent laws came under their hand?

We urge that the Patent Act be construed so as to sustain its large objectives, the ones clearly intended by Congress. To do so will confirm the patentability of microorganisms and both encourage a beneficent science and ensure that broad and forward-looking incentives remain for those who would pull the next technology, the one now invisible because still down over the horizon of the future, into view and into use.

Conclusion.

For the foregoing reasons, the judgment of the United States Court of Customs and Patent Appeals should be affirmed.

January, 1980.

Respectfully submitted,

LYON & LYON,
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